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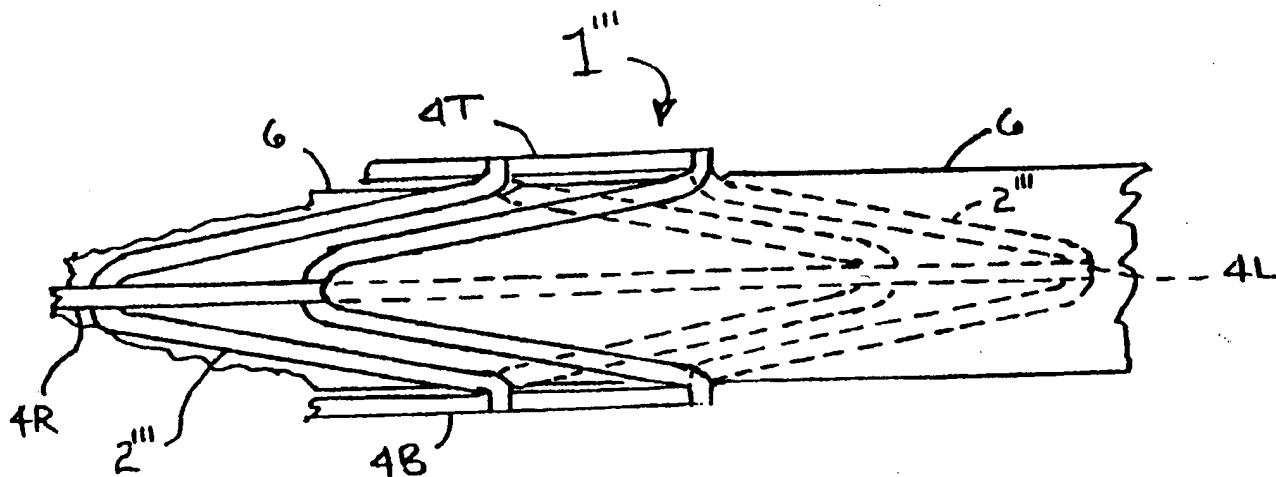
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(54) Titre : STENT MUNI DE MULTIPLES LONGITUDINAUX ONDULES

(54) Title: STENT HAVING A MULTIPLICITY OF UNDULATING LONGITUDINALS



(57) Abrégé/Abstract:

The present invention provides for an expandable stent for use in an artery or other vessel of a human body. The stent structure maintains the patency of the vessel within which the stent is expanded radially outward. One embodiment of the present invention is a stent having a multiplicity of frames joined together by at least two undulating longitudinal structures which can readily change their length in the longitudinal direction so as to provide increased longitudinal flexibility for the stent for easy passage through and placement within a curved vessel such as a coronary artery. The stent is an embodiment of the present invention having frames joined with longitudinal structures and formed from a single, thin-walled piece of metal by means of laser cutting or chemical etching. Because the stent is fabricated from a single piece of metal, it provides a multiplicity of closed perimeter cells that are formed as a continuous metal structure.

ABSTRACT

The present invention provides for an expandable stent for use in an artery or other vessel of a human body. The stent structure maintains the patency of the vessel within which the stent is expanded radially outward. One embodiment of the present invention is a stent having a multiplicity of frames joined together by at least two undulating longitudinal structures which can readily change their length in the longitudinal direction so as to provide increased longitudinal flexibility for the stent for easy passage through and placement within a curved vessel such as a coronary artery. The stent is an embodiment of the present invention having frames joined with longitudinal structures and formed from a single, thin-walled piece of metal by means of laser cutting or chemical etching. Because the stent is fabricated from a single piece of metal, it provides a multiplicity of closed perimeter cells that are formed as a continuous metal structure.

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STENT HAVING A MULTIPLICITY OF UNDULATING LONGITUDINALS

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FIELD OF THE INVENTION

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This invention is in the field of stents for maintaining patency of any one of a multiplicity of vessels of the human body.

BACKGROUND OF THE INVENTION

In the last decade, many different designs of stents have been used to maintain
5 patency of arteries and other vessels of the human body. In all such devices, hoop
strength is an important characteristic. Specifically, the stent must have enough hoop
strength to resist the elastic recoil exerted by the vessel into which the stent is placed.
The Mass stent described in the U.S. Patent No. 4,553,545 and the Dotter stent described
in U.S. Patent No. 4,503, 569 are each open helical coils. The Palmaz stent described
10 in the U.S. Patent No. 4,733,665 is of the "chinese finger" design. The Gianturco-Rubin
stent currently sold by Cook, Inc. is another stent design which like the stents of Mass,
Dotter and Palmaz does not have any closed circular member to optimize hoop strength.

The ideal arterial stent utilizes a minimum wire size of the stent elements to
minimize thrombosis at the stent site after implantation. The ideal arterial stent also
15 posses sufficient hoop strength to resist elastic recoil of the artery. Although the
optimum design for maximizing hoop strength is a closed circular structure, no prior art
stent has been described which has a small diameter when percutaneously inserted into
a vessel and which expands into the form of multiplicity of closed circular structures (i.e.
rings) which expand outward against the vessel wall.

BRIEF SUMMARY OF THE PRESENT INVENTION

20 The present invention is an expandable stent that can be used in an artery or any
other vessel of the human body which, when expanded, forms a multiplicity of generally

circular rings whose closed structure optimizes hoop strength so as to minimize elastic recoil of the vessel into which the stent is inserted. Furthermore, the structure of the stent in the present invention is initially in the form of folded ellipses or ovals which can be formed to a small diameter for percutaneous insertion by means of a stent delivery catheter. The ovals are joined to each other by either a straight or undulating shaped wires which are called "longitudinals" which serve to space the deployed rings within the vessel. Straight longitudinals are used in straight vessels and undulating longitudinals can be employed in either straight or highly curved vessels such as some coronary arteries.

Thus, an object of this invention is to provide a stent having a maximum hoop strength by the employment of closed, generally circular structures which are in fact rings.

Another object of this invention is that the rings are initially in the form of ovals at can be folded to fit onto a cylindrical structure at a distal portion of a stent delivery catheter.

A stent structure for maintaining patency of a vessel comprising a multiplicity of structures forming longitudinals extending in a substantially longitudinal direction, at least a portion of at least one of said longitudinals having an undulating shape.

A pre-deployment stent structure having a longitudinal axis comprising at least two longitudinal structures each having at least one straight section and at least one undulating section with each said straight section being joined continuously to said at least one undulating section, the straight sections of all of the longitudinal structures being generally parallel to the longitudinal axis of the stent, the undulating section of each longitudinal structure extending generally in a circumferential direction and being of a generally curved shape so as to allow each undulating longitudinal structure to readily change length during insertion of the stent structure into a curved vessel.

A balloon expandable coronary stent comprising: (a) a stent in the form of a thin-walled metal tube capable of being mounted on an expandable balloon for percutaneous delivery of the stent into a coronary artery, the stent having a plurality of zig-zag segments, the zig-zag segments capable of being expanded by the balloon; and, (b) a plurality of longitudinally undulating sections of a generally curved shape positioned between and connecting the zig-zag segments, wherein the plurality of longitudinally undulating sections can expand and contract in length while being passed through a curved coronary artery.

Still another object of this invention is that the fully deployed rings are spaced apart by means of longitudinals which are either straight or undulating wires that are placed to be generally parallel to the longitudinal axis of the vessel into which the stent is deployed.

Still another object of this invention is that the pre-deployment stent structure is formed as a single piece out of a metal tube having a smaller inside diameter as compared to the outside diameter of an expandable balloon onto which the pre-deployment stent is mounted.

These and other important objects and advantages of this invention will become apparent from the detailed description of the invention and the associated drawings

provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the stent after it has been deployed; i.e., in its post-deployment form.

FIG. 2 is a transverse cross section at section 2-2 of FIG. 1 illustrating how the longitudinals are joined to the rings.

FIG. 3 is a cross section at section 3-3 of FIG. 2 showing the joining of a single ring to the longitudinals.

FIG. 4 is a side view of the stent prior to being mounted onto a stent delivery catheter; i.e., in the form of an initial structure.

FIG. 5 is a transverse cross section at section 5-5 of FIG. 4 illustrating how the longitudinals are joined to the ovals.

FIG. 6 is a side view of a preemployment form of the stent structure in which the ovals have been folded into a small diameter cylinder that is placed around a deflated balloon situated near the distal end of a stent delivery catheter.

FIG. 7 is a partial side view of a pre-deployment stent structure showing only two of a multiplicity of folded ovals formed around an expandable balloon in which the ovals are folded in an alternative manner as compared with FIG. 6.

FIG. 8 is a side view of a post-deployment stent structure which utilizes two undulating longitudinals on opposite sides of the stent for improved placement in curved vessels.

FIG. 9 is a side view of a stent as etched out of a small diameter metal cylinder as a single piece of metal.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the cylindrical stent 1 of the present invention shown in its post- deployment configuration. The stent 1 has a multiplicity of rings 2 which are spaced apart by four wires called longitudinals. As seen in FIGS. 1 and 2, at the top of the stent is longitudinal 4T, at the bottom is longitudinal 4B, at the left side is longitudinal 4L and at the right side is longitudinal 4R. Although FIGS. 1 and 2 show 7 rings and 4 longitudinals, it is apparent that the stent can be made longer by adding rings or incasing the separation between rings. In a similar manner, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. Also variable spacing of the rings is envisioned for accomplishing a variety of purposes including increased hoop strength at a particular section of the stent. Also, it is envisioned that the two or more longitudinals could be utilized for this stent design with a maximum number being 32.

FIGS. 2 and 3 illustrate the joining of the longitudinals to the rings. Specifically the longitudinals can be placed into cutouts in the form of notches 5 located on the outside perimeter of the ring 2. The longitudinals can then be spot welded, adhesively bonded or joined by any variety of means to the rings 2. It is also envisioned that the longitudinals could be placed on the inside perimeter of the ring 2, or holes could be mechanically or laser drilled through the ring 2 for placement therethrough of the longitudinals.

FIGS. 4 and 5 illustrate a stent 1' shown in one particular form in which it could be fabricated; i.e., in an initial structure form. Specifically, FIGS. 4 and 5 show that this initial form of the stent 1' is a multiplicity of parallel ellipses or ovals 2' each oval having

the same minor axis dimension m and major axis dimension M . The oval's minor axis passes through the centre of the longitudinals 4L and 4R. The oval's major axis passes through the centre of the longitudinals 4T and 4B. It is important to note that, if it is desired to have a final outside diameter D (as seen in Fig. 2) of the ring 2 after it is fully deployed, then it can be shown that D is given by the equation $D^2 = 1/2 (m^2 + M^2)$.

To place the stent design of FIGS. 4 and 5 onto a balloon that is mounted near the distal end of a stent delivery catheter, it is necessary to fold the ovals 2' around that balloon. Specifically, the pre-deployment cylindrical stent 1" can be formed onto an expandable balloon 6 as shown in FIG. 6 by folding the ovals 2' about the dotted line F (which is the minor axis of the oval 2') as shown in FIG. 5. Specifically, as seen in FIG. 4, the top and bottom of the ovals 2' could be held stationary while the side longitudinals 4R and 4L are pushed to the left which results in the pre-deployment structure which is shown as the stent 1" in FIG. 6. An optimum design has the folded ovals 2" as shown in FIG. 6 with the stent 1" being a cylinder whose outside diameter is equal in size to the minor axis dimension m . When the balloon 6 of FIG. 6 is expanded, the pre-deployment stent 1" structure forms the post deployment stent 1 structure having circular rings 2 as shown in FIGS. 1 and 2.

The stent 1" is an alternative embodiment for a pre-deployment structure of the stent of the present invention as it is placed onto a balloon. Specifically, FIG. 7 shows 2 folded rings 2" of a multiple ring stent 1". The stent 1" being formed by holding the top and bottom of the stent 1' of FIG. 4 stationary while pushing the longitudinal 4R to the left and pushing the longitudinal 4L to the right. Like the stent 1" of FIG. 6, when mounted onto a balloon, the stent 1" has a cylindrical shape with a diameter equal to the dimension m .

FIGS. 1 to 7 inclusive illustrate stents that employ longitudinals that are formed from generally straight wires. FIG. 8 shows an alternative embodiment of a stent 10 that has two undulating longitudinals. Specifically, the left side longitudinal 14L (shown as dotted lines) and the right side longitudinal 14R are each undulating shaped longitudinals. A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

Typically, the rings and longitudinals of the stents would be made of the same material. Typical metals used for such a stent would be stainless steel, tantalum, titanium, or a shape memory metal such as Nitinol. If Nitinol is used, the stent would be heat treated into the shape at body temperature having circular rings 2 as shown in FIGS. 1 and 2. The rings could then be distorted into ovals as shown in FIGS. 4 and 5 and then mounted onto a stent delivery catheter which does not employ a balloon but is of the more general shape described in the previously cited U.S. Patent No. 4,553,545 by C.T. Dotter. Such a design would provide the desired stent structure having a multiplicity of generally circular rings instead of the Dotter design of a helical spring which inherently has a lesser hoop strength as compared to the present invention.

It should be understood that once the ovals are folded onto a stent delivery catheter, when they fully deploy, they do not form perfectly circular rings as shown in FIG. 2, but rather they are of a generally circular shape. Such comparatively small deviations from an exactly circular shape do not appreciably decrease hoop strength because they are in fact closed structures that are almost exactly circular.

It should also be understood that at least part of the end rings of the stent could be fabricated from or coated with a radiopaque metal such as tantalum or gold to

provide a fluoroscopic indication of the stent position within a vessel. However, the other rings and the longitudinals could be made from a much less dense metal which would provide less obscuration of the central region within the stent. For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings which could be formed from gold which is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively non-thrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

The dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0 mm depending on the luminal diameter of the vessel into which it is inserted. The length of the stent could be between 1 and 10 cm. The wire diameter for the longitudinals would typically be between 0.05 and 0.5 mm.

Although the designs of FIGS. 1 through 7 inclusive illustrate separate longitudinals attached to a multiplicity of rings, this invention also contemplates an initial stent structure which is chemically etched from thin-walled tubing having an oval transverse cross section. Thus the oval and longitudinals would be formed from a single piece of metal thus precluding the need for attaching the longitudinals to the rings. In a similar manner laser or EDM machining could be used to form the stent from a thin-walled tube.

It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-walled metal

cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon.

5 Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A stent structure for maintaining patency of a vessel comprising:

a frame extending around a longitudinal axis of said stent structure: and,

a multiplicity of structures forming longitudinals fixedly coupled to said frame

and extending in a substantially longitudinal direction, at least a portion of at least one of said longitudinals having an undulating shape for enhancing longitudinal flexibility.

2. The stent structure as recited in claim 1 where said frame is formed of at least a pair of longitudinally displaced frame elements, said longitudinals being secured to at least two of said frame elements.

3. The stent structure as recited in claim 2 where said frame elements are formed in a closed contour.

4. The stent structure as recited in claim 2 where said frame includes a pair of opposing end frame elements having a radiopacity value different than a radiopacity value of other frame elements forming said frame.

5. The stent structure as recited in claim 2 where said stent structure is formed from a metal having a shape memory characteristic.

6. A stent structure for maintaining patency of a vessel comprising:

(a) a frame displaceable in a radial direction for contiguous interface with an inner wall of said vessel of said human body; and,

(b) a multiplicity of longitudinals secured to said frame, at least two of said longitudinals having an undulating contour for enhancing longitudinal flexibility.

7. The stent structure as recited in claim 6 where said longitudinals extend in a substantially longitudinal direction.

5 8. The stent structure as recited in claim 6 where said frame includes a plurality of longitudinally displaced frame elements, each of said frame elements being fixedly coupled to at least one of said longitudinals.

10 9. The stent structure as recited in claim 7 where said frame elements are formed in closed contour formation.

10. The stent structure as recited in claim 7 where said frame elements are formed of wire members.

15 11. The stent structure as recited in claim 7 where said longitudinals are formed of wire members.

12. The stent structure as recited in claim 7 where said frame elements and said longitudinals are formed of a metal composition.

20 13. The stent structure as recited in claim 8 where said frame includes a pair of longitudinally displaced end frame elements having a differing radiopacity when taken with respect to at least one other frame element of said frame.

25 14. A pre-deployment stent structure having a longitudinal axis comprising at least two longitudinal structures secured to a frame extending around said longitudinal axis, each of said longitudinal structures having at least one straight section and at least one undulating section with each said straight section being joined continuously to said at least one undulating section, the straight sections of all of the longitudinal structures
30 being generally parallel to the longitudinal axis of the stent, the undulating section of each longitudinal structure extending generally in a circumferential direction and being

of a generally curved shape so as to allow each undulating longitudinal structure to readily change length during insertion of the stent structure into a curved vessel.

5 15. The pre-deployment stent structure of claim 14 wherein the undulating section of the longitudinal structures extend first in one circumferential direction and then extend in the opposite circumferential direction.

10 16. The pre-deployment stent structure of claim 14 wherein each undulating section is joined at each of its ends to a straight section.

17. The pre-deployment stent structure of claim 14, wherein each undulating structure is in the general form of a sine wave.

15 18. The pre-deployment stent structure of claim 14 formed as a one piece structure that is photo-etched from a single piece of metal.

19. The pre-deployment stent structure of claim 14 formed as a one piece structure that is EDM machined from a thin-walled tube.

20 20. The pre-deployment stent structure of claim 14 formed as a one piece structure that is laser machined from a thin-walled tube.

25 21. A pre-deployment balloon expandable stent structure adapted for percutaneous delivery to the curved coronary arteries, the stent structure being generally in the form of a thin-walled metal tube having a longitudinal axis, the stent structure having a multiplicity of closed perimeter cells, each cell having one or more undulating sections, each undulating section having a generally curved shaped and having a first end point and a second end point wherein a line drawn from the first end point to the second end point is generally parallel to the stent structure longitudinal axis.

22. The stent structure of claim 21 wherein the line drawn from the first end point to the second end point of the generally curved shape remains generally parallel to the longitudinal axis as the stent structure is expanded into its post-deployment state.

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23. The stent structure of claim 21 wherein each cell has at least one circumferentially adjacent cell which shares one undulating section.

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24. The stent structure of claim 21 wherein the undulating section of each closed perimeter cell comprises a "U" shaped curve.

25. A balloon expandable coronary stent comprising:

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(a) a stent in the form of a thin-walled metal tube capable of being mounted on an expandable balloon for percutaneous delivery of the stent into a coronary artery, the stent having a plurality of zig-zag segments, the zig-zag segments capable of being expanded by the balloon; and,

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(b) a plurality of longitudinally undulating sections of a generally curved shape positioned between and connecting the zig-zag segments, wherein the plurality of longitudinally undulating sections can expand and contract in length while being passed through a curved coronary artery.

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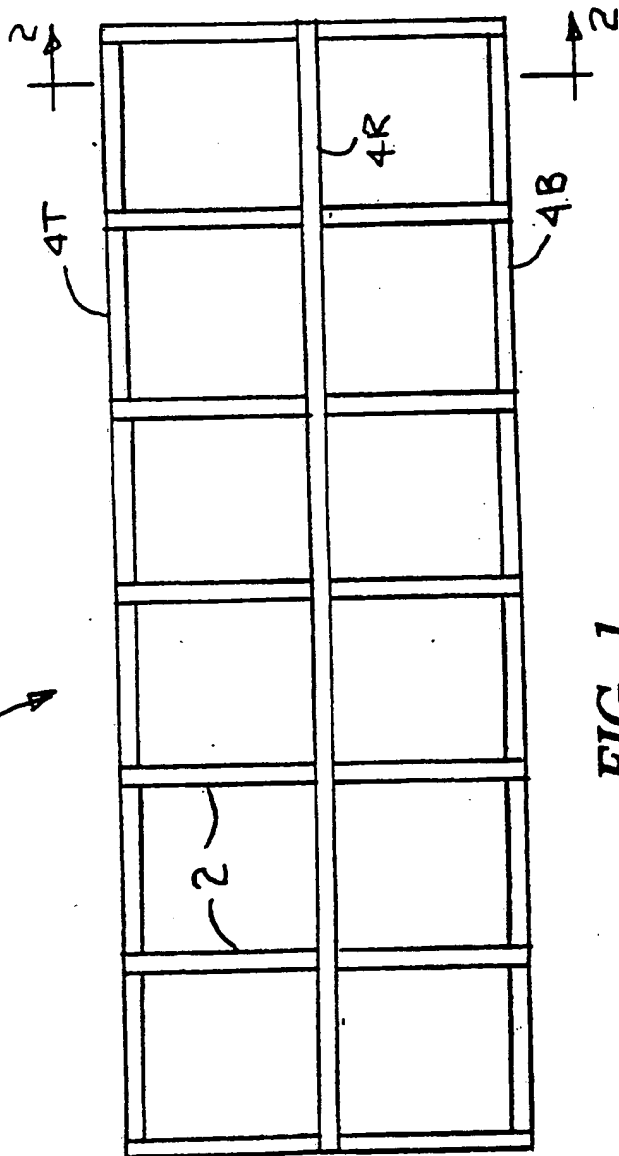


FIG. 1

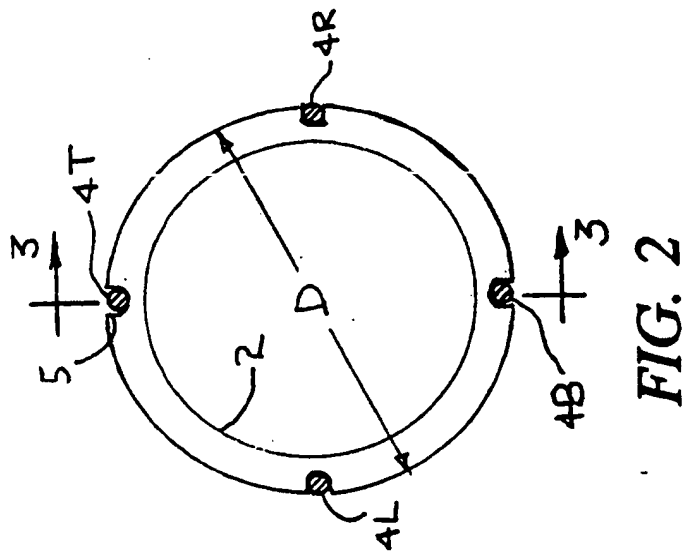


FIG. 2

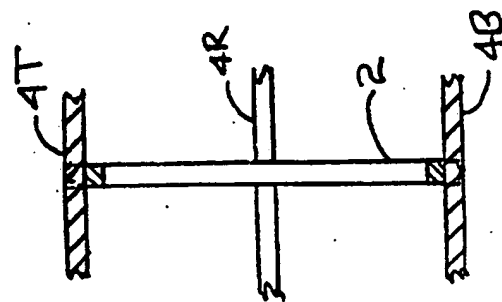


FIG. 3

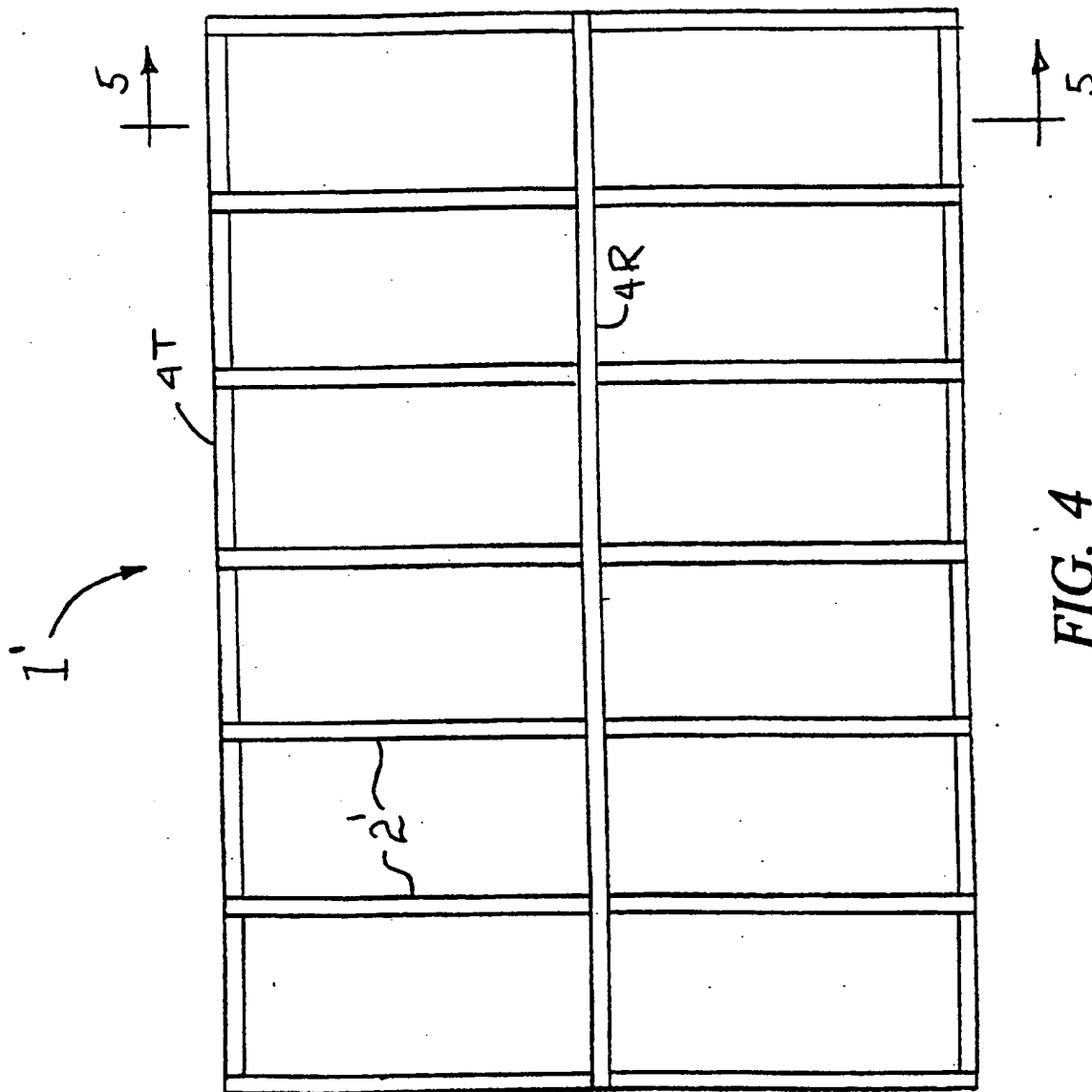


FIG. 4

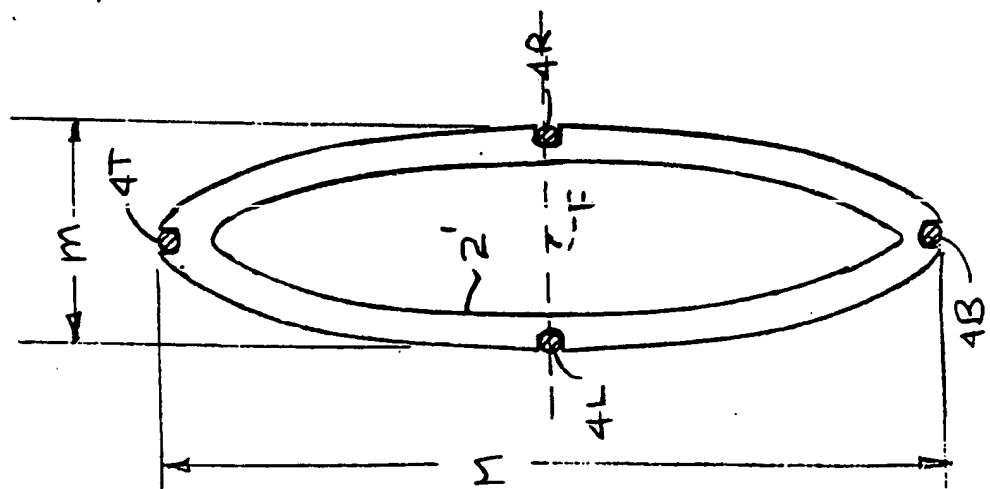


FIG. 5

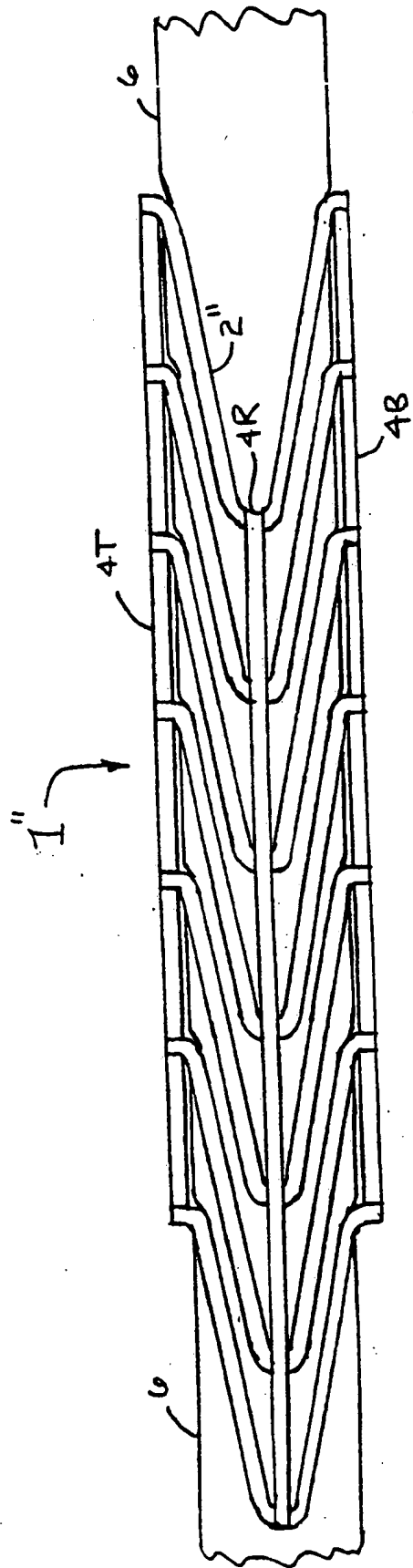


FIG. 6

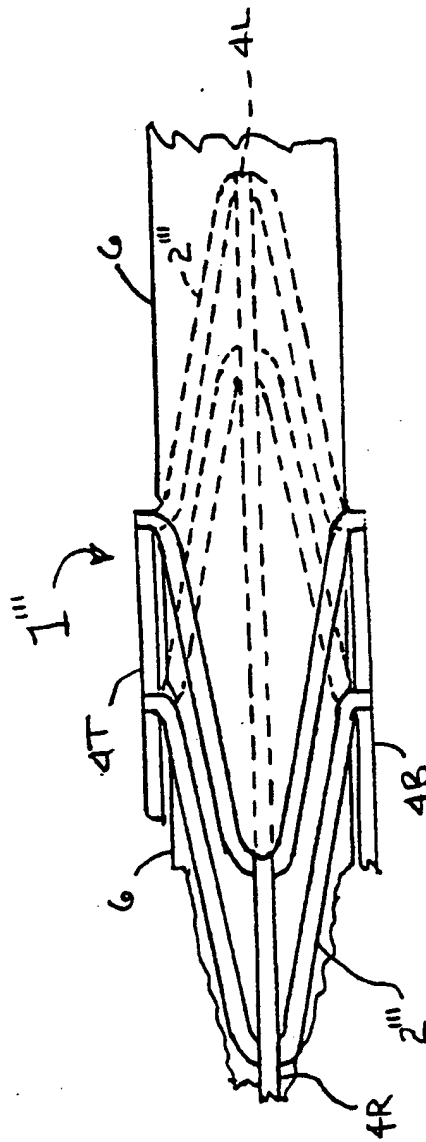


FIG. 7

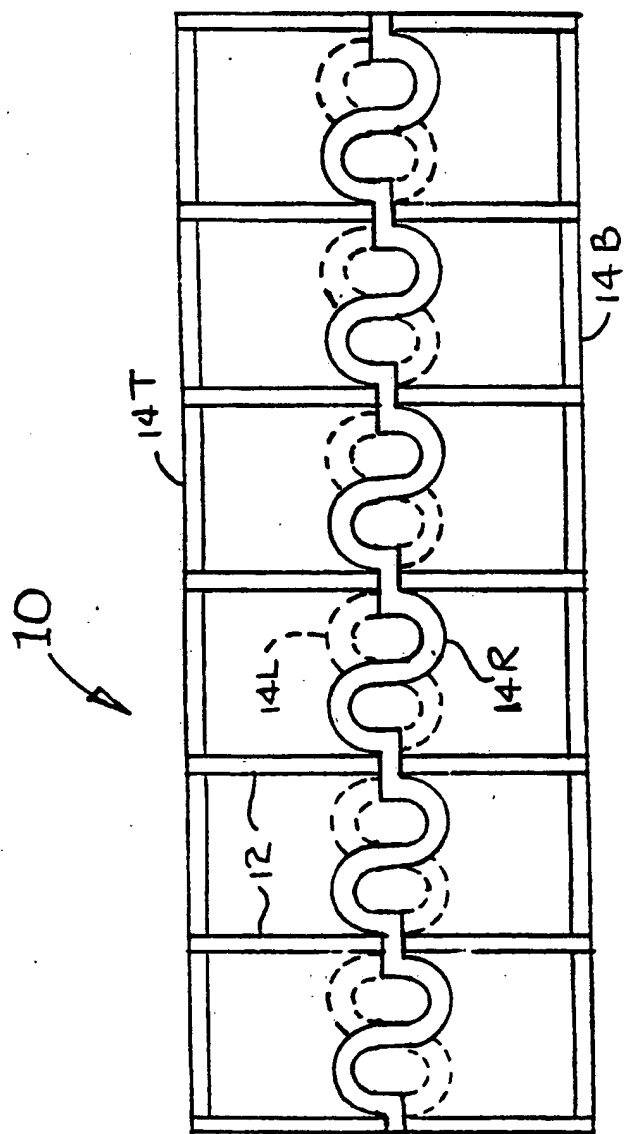


FIG. 8

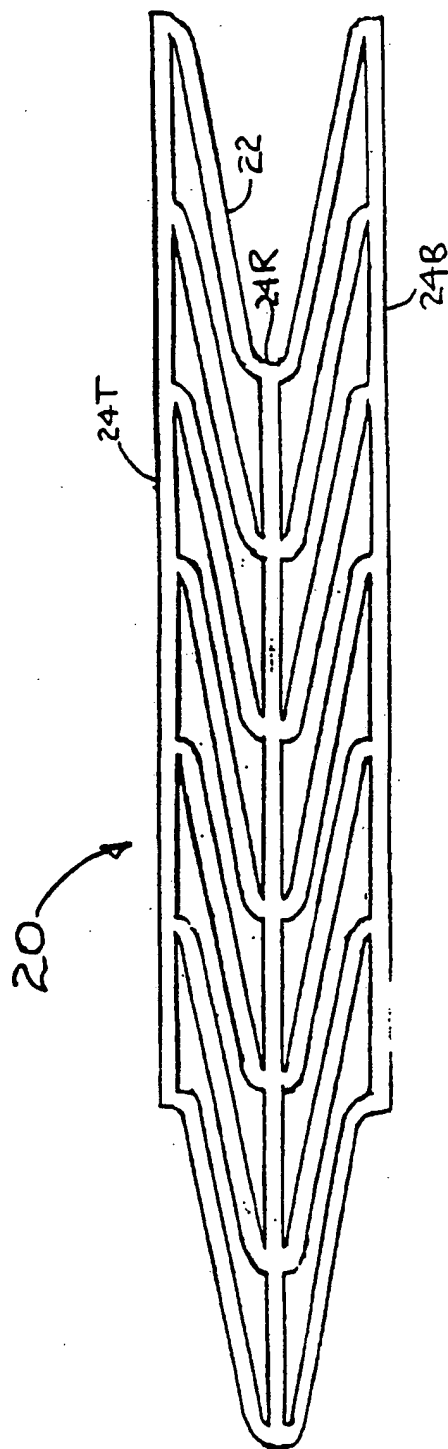


FIG. 9

